UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION

/2016

MEMORANDUM

Subject:	Name of Pesticide Product:	A20903A
	EPA Reg. No./File Symbol:	100-RLIT
	DP Barcode:	D430648
	Decision No:	510948
	PC Codes:	060109 (difenoconazole), 129223 (sedaxane), 071503 (fludioxonil)

From: Eugenia McAndrew, Biologist

Through: Masih Hashim, Ph. D., Team Leader Toxicology
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Jacquelyn Marchese, RM Team 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

Applicant: Syngenta Crop Protection, LLC
410 Swing Road
P.O. Box 18300
Greensboro, NC 27419-8300

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt
Fludioxonil	2.17
Sedaxane	2.17
Thiamethoxam	22.80
Other ingredients:	72.86
Total:	100.00%

ACTION REQUESTED: The Risk Manager requests review of acute tox data submitted for 100-RLIT.

BACKGROUND: Syngenta Crop Protection, LLC has submitted acute toxicity studies with MRIDs 497122-06 to -11 to support the registration of the proposed product, A20903A, EPA File Symbol 100-RLIT. The submission includes a basic CSF and one alternate CSF dated August 10, 2015, label, data matrix and company letter. The CSFs must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

GLP: Yes

DEVIATIONS: None

LABELING:

DATA EVALUATION RECORD

Product Reg. No.: 100-RLIT
Product Name: A20903A

1. DP BARCODE: 430648

2. PC CODES: 071503, 129223, 060109

3. CURRENT DATE: February 2016

4. TEST MATERIAL: Sedaxane/ fludioxonil/ thiamethoxam FS A20903A [Batch ID SMU4JP004; PSL Reference # 150224-11H; sedaxane 2.15% w/w or 24.7 g/L, SYN508210 (trans-isomer of sedaxane) 1.86% w/w or 21.4 g/L, SYN508211 (cis-isomer of sedaxane) 0.290% w/w or 3.33 g/L, fludioxonil 2.17% w/w 24.9 g/L and thiamethoxam 23.6% w/w or 271 g/L; density 1.106 g/ml; red liquid]

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Product Safety Labs Study #40541/April 22, 2015 OCSPP 870.1100; OECD 425	49712206	LD_{50} Females > 2000 mg/kg 6 animals were tested at Limit doses of 5000 or 2000 mg/kg Mortality: 5000 mg/kg: 1/1 2000 mg/kg: 0/5 5000 mg/kg (1 animal): The animal died within 5 ½ hours of test substance administration. Prior to death, the animal was hypoactive and exhibited irregular respiration, hunched posture and slight tremors. Gross necropsy revealed a distended stomach filled with fluid and fluid filled intestines. 2000 mg/kg (5 animals): All animals survived and gained weight. Clinical signs of toxicity included red feces in all animals and hypoactivity and irregular respiration in 3/5 animals with recovery by day 3. No gross abnormalities were noted at necropsy.	III	A
Acute dermal toxicity / rat	49712207	LD_{50} > 5000 mg/kg (both sexes)	IV	A

Product Safety Labs Study #40542/April 22, 2015 OCSPP 870.1200; OECD 402		All animals survived and gained weight. Dermal irritation (erythema) was noted at one female dose site on day 1 only. No other clinical signs of toxicity were observed. No gross abnormalities were observed at necropsy. Red staining was noted at all dose sites.		
Acute inhalation toxicity / rat Product Safety Labs Study #40543/April 22, 2015 OCSPP 870.1200; OECD 403	49712208	LC_{50} > 5.14 g/L MMAD = 2.09µm GSD = 2.29 All animals survived. Two animals lost weight by day 3 but all animals gained weight by day 7 and thereafter. All animals exhibited irregular respiration with recovery by day 2. No gross abnormalities were observed at necropsy.	IV	
Primary eye irritation / rabbit CiToxLAB Hungary Ltd. Report #15/079-005N/July 15, 2015 OCSPP 870.1300; OECD 405	49712210	3 males tested; ocular anesthetic used pH 6.21 No corneal opacity, iritis or positive scores were observed. Conjunctivitis (redness and/or chemosis) with score of 1 was observed in all eyes at one and 24 hours. Discharge score of 2 (not a positive effect) was noted in all eyes at one hour. All eyes were free of irritation by 48 hours.	IV	A

Primary dermal irritation / rabbit Product Safety Labs Study #40544/April 22, 2015 OCSPP 870.2500; OECD 404	49712209	PDI = 0.0 3 females tested No dermal irritation was observed at any treated site.	IV	A
Dermal sensitization/mouse Product Safety Labs Study #40545/April 22, 2015 OCSPP 870.2600; OECD 429	49712211	Positive for sensitization % tested SI Value* 25% 0.83 50% 1.07 100% 0.77 *Stimulation Index values < 3 are are negative results. Results of concurrent positive control study are acceptable.	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap W = Waived